Talking with Stakeholders about FDA Modernization

Open Public Meeting
April 28, 1999
Boston

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Thank you for the opportunity to provide these comments on FDA's progress in implementing the FDA Modernization Act. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world.

Introduction

Today FDA is faced with several challenges. FDA is charged with implementing a complex and demanding statute. It wields enormous economic power over a substantial portion of the marketplace. Public expectations of the agency's ability to provide the most technologically advanced products, risk-free, and immediately—can be unrealistic. And the agency is under constant scrutiny by the Congress, the public, and we, the stakeholders.

Such challenges require optimal levels of communication, cooperation, consultation, and collaboration. We support the agency's ongoing attention to seek improvements in these areas and welcome the opportunity to provide suggestions.

Overall General Recommendations

Faced with shrinking resources, increased statutory obligations and public expectations, we recommend that the agency (1) devote its resources to core statutory obligations, (2) focus its resources on highest risk products, (3) maximize the tools of FDAMA, (4) continue to seek improvements through reengineering and other management initiatives, (4) leverage resources from both the public and private sectors, (5) cease activities that are not essential to carrying out the law, and (6) seek additional funding from Congress for device reviews.

Ongoing General Concerns

Review Times

While the majority of devices are regulated by CDRH, there are a number of devices that are regulated by the Center for Biologics Evaluation and Research. The device provisions of FDAMA also apply to these devices. Not surprisingly, industry's ongoing concerns with device reviews conducted by CBER do not differ significantly from the concerns expressed with regard to CDRH. Product review times top the list of issues for both Centers. However because medical devices are not CBER's primary focus. Consequently until very recently, little attention has been paid to the medical device industry's concerns over the increasing product review backlog at CBER.

Changes are in progress. CBER has held several meetings to gain a better understanding of the concerns of the device industry. As a result of these interactions with industry, CBER is now focusing on improving its device review activities through the development of a CBER Device Action Plan. The plan, which is greatly needed and long overdue, is intended "to facilitate the implementation of the device provisions of FDAMA and to assure consistency of policy and procedures between CBER and CDRH". This is a laudable goal and we look forward to learning more about the specifics of the plan.

Any plan is only as good as the input provided to develop it. We remind CBER of the necessity to communicate, collaborate and consult with stakeholders in the development of the device action plan. It will be a challenge for CBER to involve industry as a partner in the development of a device action plan. Part of that challenge will require to CBER think beyond its traditional ways of doing things and allow its stakeholders both in the medical device industry and the blood banking community to help set realistic, science based goals for its device-related functions.

Development Times

Another ongoing general concern of the medical device industry is development time—the time it takes to produce the data and other information required by FDA to meet the threshold level of evidence necessary for the review to begin. This issue is tied to Section 205 of FDAMA that FDA shall consider the "least burdensome" appropriate means to demonstrate device effectiveness or substantial equivalence to predicate devices with differing technological characteristics. The least burdensome concept does not reduce the scientific standard for effectiveness; this concept is intended to carry through Congress' longstanding purpose included in the "Medical Device Amendments of 1976" to avoid over-regulation of devices. It is also tied to President Clinton's statement upon signing FDAMA that the law would "ease the regulatory burden on industries . . .." Furthermore, the overall goal of speeding beneficial technology to patients is one that is greatly affected by the length of time it takes to meet FDA's threshold review requirements.

HIMA chairs an industry-wide "Least Burdensome Industry Task Force" that has submitted a proposal to the agency on recommended approaches for how this concept should be implemented by FDA. We have urged the FDA to carefully consider that proposal and have requested a meeting to exchange ideas concerning "least burdensome."

CBER should also ensure that its reviewers are adequately trained on and make appropriate use of the "least burdensome" concept. Often, CBER requests extensive studies when other less burdensome studies could demonstrate the device safety and effectiveness. This often discourages manufacturers who will often then develop and market products that could improve the safety of the nations' blood supply outside of the U.S. We recommend that CBER participate in any discussions between CDRH and industry on "least burdensome."

Guidance Documents

Although long product review times remain an issue of primary concern, manufacturers also note an apparent disconnect between what CBER wants in product submissions and

what manufacturers think CBER wants in product submissions. After waiting six months to receive questions on a submission, on average it takes a manufacturer three to six months to respond to CBER's queries. CBER cites poor product submissions as the reason the delay. We believe that part of the problem is lack of clear guidance on submission requirements. CBER and the industry must work together to develop guidance documents that clearly define what is expected of both parties.

Review Time Metrics
Any good plan includes some way to measure progress. Traditionally industry has measured FDA progress by monitoring product review times. Complete, timely data on CBER device review times is generally not available. CBER should publish its review time metrics on a regular basis to provide both the Agency and industry a yardstick to gauge the progress made.

Responses to Specific Questions for April 28, 1998 Stakeholders' Meeting

In the *Federal Register* announcement of the meeting, FDA asked for specific input on five questions. HIMA's response follows:

Question #1: What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?

One of the issues this question raises, as a general matter, is the need for FDA to be vigilant in ensuring that it is incorporating the appropriate level of science in its decision-making processes. For instance, the regulatory requirements for PMA approval incorporate a "reasonable assurance" of safety and effectiveness standard—not an "absolute assurance." FDA must ensure that whatever quantum of science it applies to its decision-making must be within the regulatory construct of the law. Scientifically based conclusions must represent a balance between risks to public health and benefits to public health.

In addition, as a government agency, there will always be financial constraints to FDA's ability to hire leading experts. The agency will seldom be able to compete with the resources of academia or industry. However the key to incorporating state-of-the-art science into the FDA decision-making process lies in the ability or reviewers to understand data, interpret results and ask appropriate questions. FDA should focus on developing and cultivating these skills in its review staff.

Specific actions that address this question are as follows:

Leverage Industry Resources—Company tutorials, vendor days, cosponsored educational workshops, etc.
HIMA proposes that FDA take advantage of industry resources to expand its own scientific base of knowledge. Industry is willing to bring scientific experts into FDA to provide state-of-the-art information to staff. CDRH vendor days have been a very successful

mechanism to provide "hands-on" exposure to actual devices and demonstrations from industry. We recommend those be continued and expanded to include CBER. Cosponsored educational workshops are another vehicle for dissemination of scientific information. HIMA is working with the agency to develop a "Cooperative Research and Development Agreement" (CRADA) to fund such workshops.

Outside Experts—Government Agencies, Academia, the Private Sector, Scientific Advisory Panels

Due to budgetary constraints, the government will never have adequate resources to hire the best scientists in all the disciplines that are required for the wide variety of FDA-regulated products. Therefore, FDA should continue to strengthen its use of and relationships with its sister governmental agencies such as the National Institutes of Health. The agency should also use the expertise resident in its own scientific advisory panels. Consulting contracts with academia and private sector scientists are additional ways to meet this need.

In order for the agency to have greater access to private sector resources, we suggest reviewing the current conflict-of-interest policy to determine whether it can be amended to allow more flexibility in the hiring of outside experts. We believe there may be many situations where experts with some degree of conflict-of-interest may still be acceptable provided there is full disclosure.

Continuing Education for Staff

We recommend that FDA require staff physicians to participate in Continuing Medical Education—preferably in the areas of expertise they are required to use in their positions. Members of industry report instances where medical officers within FDA are not familiar with current medical procedures and practices. The lack of up-to-date medical knowledge causes delays in the review process. Similarly, FDA should at least encourage, if not require, its scientists to keep current in their field by taking advantage of seminars and other educational opportunities.

Optimal Collaboration Meetings

The need for knowledge about state-of-the-art science often arises during the course of the presubmission meetings (FDAMA meetings) for (1) determining the type of scientific evidence required to show device effectiveness and (2) agreeing on the investigational plan. Both industry and the agency can optimize these meetings by ensuring that scientific experts, statisticians, and other necessary experts are present and fully prepared to discuss the scientific issues.

FDA's Own Excellent Scientists

HIMA supports increased funding for the agency targeted to device reviews. If FDA receives such an increase, some portion should be devoted to hiring reviewers with excellent scientific backgrounds. The decisions of current (and future) reviewers and other staff involved in the review process should be respected and not "second-guessed" by staff who may become involved in the process at a later point. Industry reports incidents when

this has happened, causing unnecessary disruption and delay. The agency should give deference to the decisions of its scientists and not allow another scientist's subsequent view or opinion regarding an aspect of the process to prevail unless there is a clear public health or safety issue.

Standards for High Risk Devices
Many scientific experts, including FDA's own, are substantially involved in developing standards for medical devices, or portions thereof, as part of national and international consensus committees. Scientific issues associated with such standards are debated and discussed in an atmosphere not governed by a single company's product, government entity or academic institution. Such standards and industry's declaration of conformance thereto are effective surrogates for FDA's independent scientific review. We recommend, therefore, that both industry and the agency increase their participation in standards-setting bodies, that FDA continue to recognize such standards and defer to them in the application process, and that the focus be on standards-setting activities involving high risk devices since that is the area of greatest return for both the agency and industry.

Question #2: What actions to you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?

This question first asks for ways to improve FDA's access to scientific information. This was addressed in the previous question. The second part of this question deals with FDA's public health responsibilities through a product's lifecycle. This part of the question raises again the need for FDA to focus on the principles of risk assessment embodied in the regulatory scheme and to train its staff to ask appropriate questions related to risk assessment.

Optimal Use of Staff College and Staff Training
FDA has existing mechanisms in place to facilitate the exchange and integration of scientific information. Those include its staff college and training programs. We recommend that the agency, if it has not already done so, adopt private sector approaches to these mechanism. They include "Train the Trainer" programs—where one person is trained to return to the workplace and conduct training for the rest of the staff; dissemination of the learning—persons trained return to the workplace and communicate orally, in writing, or via e-mail the main points of the training; diversification of attendance—all levels of staff are sent to training or rotated through—not just senior staff. In addition, we recommend that FDA ask industry to provide scientific experts with practical, relevant experience to participate in training programs.

Question 3: What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?

Increasingly, consumers are becoming better educated about their own health and personal medical problems. The availability of Internet resources can result in patients having more information than their physicians. This creates a demand in the marketplace for additional

information by both the consumer and the physician—a demand that will largely be met by the marketplace, not a government agency like FDA. There is no magic bullet that will fully educate the public about how to balance risks and benefits.

For CBER this is difficult issue. Some consumers believe that products including the nations blood supply should be completely risk-free. FDA can play a useful role in educating the public generally about the risks and benefits of its regulated products and about continuing efforts to reduce the risks associated with these products.

FDA Web Site
FDA could provide general guidelines for consumers on its web site addressing the concept. A list of questions for consumers to ask may be appropriate. FDA may also wish to use its web site to describe, in laymen's terms, the nature of its own responsibilities to balance risk and benefit and how difficult that is at times and that no product is completely risk-free. FDA could also provide Internet links to other sites that may contain more specific information about a particular condition, disease, or product. Links could be provided to professional societies, patient groups, as well as individual companies.

Question 4: Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

Continuous FDAMA implementation and reengineering
CBER should continue to implement the tools of FDAMA and to adopt CDRH reengineering initiatives in order to free up resources. This includes taking a critical look at ways to (1) expand the list recognized standards and increase their use by industry, (2) make optimal use of early collaboration meetings, and (3) harmonize regulatory requirements.

Industry/Agency Training, Education, Communication
In order to maximize the tools of FDAMA and to create the most efficient systems possible, FDA staff must be adequately trained in their application. In addition, industry must also be educated on the tools available as well as the agency's expectations

Elimination of Unnecessary or Redundant Functions
FDA should closely examine all of its functions and determine which are not essential to carrying out its core statutory obligations. FDA should rid itself of all but absolutely necessary functions mandated by law.

Continuation of Inspection Initiatives

HIMA has participated in several successful initiatives to improve FDA's device inspection process. Some of these efforts are outlined in the testimony of Nancy Singer, Special Counsel for HIMA addressing these initiatives is being filed separately under Docket No. 99N-0386. These initiatives have not included CBER device inspections.

CBER should review the testimony and adopt those elements that would enhance CBER's inspection program.

With regard to the statutory mandate to conduct inspections biennially for manufacturers of Class II and Class III devices, we note that in the Plan, the agency hinted that it might take a look at determining what type of statutory flexibility might be desirable in this area. We believe that the agency should have the discretion to determine the frequency of inspections based on risk and recommend consideration of a statutory amendment to this effect.

Question #5: Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?

Need for true consultation, not just comments
The statute uses the term "consultation" in connection with FDA's 406(b) obligation. This means more than just listening to or reading comments. If Congress had intended the FDA only to seek public comments, it could have done so. *Webster's* dictionary defines consultation as "meeting to discuss, decide, or plan." Discussion, decision-making, and planning all involve brainstorming, a give-and-take exchange of ideas, dialogue. These meetings do not allow for that kind of activity. We urge the agency to engage in consultation with its stakeholders that may be more meaningful and productive than the type of "consultation" exemplified by these meetings.

No or little feedback from agency on previous comments from industry
HIMA has commented extensively on the regulations, notices, and guidance documents published by CDRH to implement FDAMA. It is unclear what input CBER has had in the development of these documents.

In some cases, it appears that our comments have not been acknowledged. While we do not expect all of our comments to be adopted, we do believe that, especially on key issues, the process would benefit from a true dialogue with industry and other interested parties. A true dialogue is especially important when there are documents that CBER may be reluctant to adopt. It is important for industry to understand the basis CBER's reluctance.

Agency and Industry Focus on Important Issues
We have tried unsuccessfully to establish a working dialogue with the agency on several key initiatives such as the "least burdensome" concept. We fail to understand how such an important concept would not benefit from the synergy of a joint working group. Several successful precedents include agency-industry working groups on the Product Development Protocol (the working group received a Vice President Gore "Hammer Award") and "When to File a 510(k) for a Modification." These should serve as models for similar activities that should have been undertaken to help develop FDAMA implementation documents. We urge the agency to support and encourage future agency-

industry working groups. We believe such groups are particularly useful for difficult and complex issues and issues with the most resource-saving potential.

HIMA Questionnaire

HIMA is in the process of obtaining feedback from its member companies on their experiences with FDAMA. Attached is a copy of that questionnaire. We intend to share the results of the questionnaire with the agency and will consider polling our members on a periodic basis on the same issues.

Conclusion

We thank the agency for this opportunity to provide our ideas and comments. We look forward to working with CBER to:

- implementation of appropriate provisions of FDAMA
- utilization of relevant CDRH reengineering initiatives
- develop and implement a device action plan that appropriately focuses CBER's device related functions

So that together we can eliminate the product review backlog and significantly reduce product review time.